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EXAMINER	
BHAT, NARAYAN KAMESHWAR	
ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)
	10/597,954	ABUDOKIRIM ET AL.
	Examiner	Art Unit
	NARAYAN BHAT	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *17-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)	
1) ☒ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.	6) ☐ Other: _____.

Continued Examination under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 3, 2010 has been entered.

Claim status

2. Claims 1-20 are pending in this application. Claims 1 and 4 are amended. The claim amendments have been reviewed and entered.

3. Claims 17-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, **without** traverse in the reply filed on September 11, 2008 and made final in the office action mailed November, 19, 2008.

4. Claims 1-16 are under prosecution.

Rejections withdrawn

5. The previous new matter rejection of claims 4, 12 and 15 under 35 USC 112 First Paragraph has been withdrawn in view of claim amendments. The previous rejection of claims 1-16 under 35 USC 112 Second Paragraph has been withdrawn in view of claim amendments. The previous rejection of claims 1-3, 5-7 and 10-16 under 35 USC 102(b) as being anticipated by Tennikova has been withdrawn in view of claim amendments.

The previous rejection of claim 1 under 35 USC 102(b) as being anticipated by Hatch has been withdrawn in view of claim amendments. The previous rejection of claims 1-4, 8 and 9 under 35 USC 103(a) as being unpatentable over Tennikova in view of Urthaler has been withdrawn in view of claim amendments.

Claim Interpretation

6. The apparatus of claim 1recite features both structurally and functionally. However, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function (In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997), MPEP 2114). Therefore instant claims are rejected over the structural components taught in the prior art rather than their intended use.

The recitation of "the monolith structure is capable of adsorbing nucleic acids in the presence of potassium ions and is capable of releasing nucleic acids in an essentially salt-free solution" of claim 1 is a functional recitation of the monolith structure because neither "potassium ion" nor "salt free solution" are structural components of the apparatus. Furthermore, the recitation of "adsorbing nucleic acids in the presence of potassium ions" and releasing nucleic acids in an essentially salt-free solution" are process steps and as described above do not further define the claimed apparatus.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following rejection is made as if "potassium ion" and "salt free solution" are the required structural components of the apparatus of claim 1.

9. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tennikova et al (J. High Resol. Chromatogr., 2000, 23, 27-38, cited in the previous office action) in view of Hatch (USPN 6,238,565 issued May 29, 2001, cited in the previous office action) further in view of Sauer et al (USPGPUB 2003/0032147, filed, May 27, 1999).

Tennikova, Hatch and Sauer teach an apparatus for separating and purifying nucleic acids and therefore are analogous arts.

The apparatus of claim 1 has following structural components: a) an integral monolith structure comprising macro-pores continuously extending from one end of the monolith structure to the other end and corresponding to the sizes of nucleic acids and b) the macropores having a diameters of about 10 nm to about 100 nm or about 100 nm to about 1 um or about 1 um to about 10 um or about 10 um to about 100 um.

Regarding claim 1, Tennikova teaches an apparatus for separating and purifying nucleic acids comprising following structural components (Fig. 4, right panel).

Regarding an integral monolith structure, Tennikova teaches an integral monolith structure (i.e., monolithic continuous structure), wherein macropores continuously extending from one end of the monolith structure to the other end (Fig. 4, right panel, and Abstract, pg. 29, column 2, paragraph 3, pg. 32, column 2, paragraph 2).

With regard to the limitation of "the monolith structure corresponding to the sizes of nucleic acids" it is noted that the instant claim as recited do not require nucleic acids as the structural components of the claimed apparatus, but rather capable of separating the size of the nucleic acids. Furthermore, instant claim 1 as recited does not require a plurality of integral monolith structure each specific for a particular size nucleic acid.

With regard to said limitation, Tennikova teaches that the monolith structure is configured so that nucleic acids corresponding to macropore of 0.5 um can be retained by allowing a solution containing nucleic acids (i.e., different size oligonucleotides) to be separated to pass there through (Fig. 7, see the legend and pg. 32, column 2, paragraph 2 and pg. 33, column 2 and paragraph 1). However, Tennikova does not teach specifically that the monolith structure corresponds to sizes of the nucleic acids.

Regarding the diameter of macro pores, Tennikova teaches that the average macropore size, (i.e., diameter) is about 0.5 um (Fig. 3b and pg. 32, column 2, paragraph 1, line 6). The diameter of the macropore of about 500 nm is in the range of about 100 nm to about 1 um as claimed.

With regard to the limitation of "the monolith structure is capable of adsorbing nucleic acids in the presence of potassium ions and is capable of releasing nucleic acids in an essentially salt-free solution", it is noted that it is a functional recitation of the monolith structure because neither potassium ion nor salt free solution are structural components of the claimed apparatus. Furthermore, the recitation of "adsorbing nucleic acids in the presence of potassium ions and releasing nucleic acids in an essentially salt-free solution" are recitation of process steps (process steps are underlined by the Examiner), which does not further define the claimed apparatus. The teachings of binding (i.e., adsorbing) nucleic acids in the presence of NaCl and an eluent comprising salt buffer solution of Tennikova (Fig. 7) meet the claimed functional recitation.

However, if Applicant amends the claim 1 requiring "potassium ions" and "a salt free solution" as the structural components, it is noted that Tennikova does not teach potassium ions and eluent comprising a salt free solution.

As described above, Tennikova does not teach monolithic structure corresponding to the sizes of nucleic acids. However, monolithic structure corresponding to the sizes of nucleic acids was known in the art at the time the claimed invention was made as taught by Hatch.

Hatch teaches an apparatus for separating and purifying nucleic acids comprising a monolithic column (i.e., an integral monolithic structure) having a pore size less than 5000 nm range to down to 10 nm range (column 8, lines 1-5), which is in the range of diameter of about 10 nm to about 100 nm, or about 100 nm to about 1 micrometer or about 1 micrometer to about 10 um.

Regarding the limitation of "monolithic structure configured to size of the nucleic acids", as described above, it is noted that claim 1 as recited does not require a plurality of integral monolith structure each specific for a particular size nucleic acid but requires an integrated monolith structure. However, Hatch teaches that for separation of about 300 bp DNA requires an interstitial distance of 1 um, whereas for separation of 1,000 bp DNA require an interstitial distance of about 1 to 3 um (column 3, lines 38-54), suggesting a selecting the interstitial distance according to the size of the nucleic acids. Hatch also teaches selecting monolithic column having pores of about 1 um for separating 2,072, 2,647, and 3,147 base pairs DNA (column 8, lines 1-30). One having ordinary skill in the art would recognize based on the combined teachings of requiring different pore size for separating different size nucleic acids and selecting the monolithic column with pore diameter of 1 um for separating nucleic acids of different size of Hatch encompasses monolithic structure corresponding to the size of the nucleic acids. Hatch also teaches selecting monolithic structure having appropriate pore size able to separate and detect a variant DNA (i.e., a hetero duplex) from a wild type DNA(i.e., a homo duplex DNA; Figs. 3A and 3B and Example 3).

As described above, both Tennikova and Hatch teach a monolithic column and Hatch teaches that the monolithic column having appropriate pore size allows separating a variant DNA from wild type DNA thus providing motivation to one of ordinary skill in the art to include the monolithic structure of appropriate pore size for separation and purification of DNA in the apparatus of Tennikova.

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to include the monolithic structure of appropriate pore size of Hatch in the apparatus of Tennikova with a reasonable expectation of success with the expected benefit of having monolithic structure of appropriate pore size for detecting the variant DNA as taught by Hatch (Figs. 3A and 3B and Example 3). An artisan having ordinary skill in the art would have a reasonable expectation of success because it merely involves substitution of one monolithic structure for the other which is routinely practiced in the art as exemplified by Hatch (e.g., see Examples 1 and 2).

As described above, if Applicant amends the claim 1 requiring "potassium ions" and "a salt free solution" as the structural components of the apparatus of claim 1, it is noted that Tennikova in view of Hatch does not teach the potassium ions and eluent comprising the salt free solution.

However, the potassium ions for adsorbing the nucleic acids and the salt free solution for releasing the nucleic acids were known in the art at the time the claimed invention was made as taught by Sauer.

Sauer teaches an apparatus for separating and purifying nucleic acids comprising silica membranes and further teaches adsorbing the plasmid DNA to the membrane in the presence of potassium ions (i.e., potassium thiocyanate; Example 2 and paragraphs 0014 and 0133). Sauer also teaches that in the presence of potassium ions plasmid DNA selectively binds to the silica membrane (Example 2). Sauer also teaches pure water as an eluent for releasing the plasmid DNA from the silica membrane (paragraphs 0022 and 0074). The pure water of Sauer encompasses a salt free solution.

As described above, Tennikova, Hatch and Sauer teach an apparatus for separating and purifying nucleic acids and Sauer teaches that the potassium ions allows specific binding of plasmid DNA to silica particles. Tennikova teaches that the monolithic structure comprises silica (Fig. 3b and pg. 33, section 4.1) and further teaches separating plasmid DNA on the monolithic structure (Abstract). Having the potassium ions of Sauer for binding of plasmid DNA would be beneficial to Tennikova for specifically binding plasmid DNA to the monolithic structure, thus providing motivation to one of ordinary skill in the art to include the potassium ions in the apparatus of Tennikova.

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to include the potassium ions of Sauer in the apparatus of Tennikova with a reasonable expectation of success with the expected benefit of having potassium ions for specific binding of plasmid DNA as taught by Sauer (Example 2). An artisan having ordinary skill in the art would have a reasonable

expectation of success because it merely involves substitution of one monovalent ion (i.e., sodium ion) for another monovalent ion (i.e., the potassium ion) which is routinely practice in the art as exemplified by Sauer.

The teachings of Tennikova, Hatch and Sauer regarding dependent claims 2-16 are discussed below.

Regarding claim 2, Tennikova teaches that the monolith structure employs silica (pg. 33, section 4.1) or a hybrid material containing an organic material and silica (Fig. 3b and pg. 33, section 4.1).

Regarding claims 3 and 7, Tennikova teaches that the porous body of the monolith structure has micro pores (i.e., small globules) in the macro pores (Fig, 3b and pg. 29, column 1, paragraph 1).

Regarding claims 4, 8 and 9, Hatch teaches that the porous body of the monolith structure has a size of less than 10 nm (column 8, lines 1-5), which encompasses a micropore as recited in the instant claim.

Regarding claims 5 and 10-12, Tennikova teaches disc formed by monolith structure and further teaches disc is placed in a column tube to form a monolith solid phase column (Fig. 2, pg. 28, column 1, paragraph 2, column 2 and paragraph 3)

Regarding claims 6 and 13-16, Tennikova teaches disc formed by monolith structure (Fig. 2, pg. 28, column 1, paragraph 2) and further teaches monolith solid phase column formed by detachably attaching a base formed with the monolith structure to a cylindrical body having the top and the bottom opened (Fig. 2, See the

CIM monolith disks and dedicated cartridge with open end and pg. 28, column 2, paragraph 2, lines 1-3).

Response to Remarks from the Applicant

Claim Rejections - 35 USC § 112 First Paragraph

10. Applicant's arguments filed February 3, 2010 with respect to claims 4, 12 and 15 rejected under 35 USC 112 First Paragraph have been fully considered (Remarks, pg. 6, paragraph 2) and are moot in view of withdrawn rejection necessitated by claim amendments.

Claim Rejections - 35 USC § 112 Second Paragraph

11. Applicant's arguments filed February 3, 2010 with respect to claims 1-16 rejected under 35 USC 112 Second Paragraph have been fully considered (Remarks, pg. 6, paragraph 3) and are moot in view of withdrawn rejection necessitated by claim amendments.

Claim Rejections - 35 USC § 102

12. Applicant's arguments filed February 3, 2010 with respect to claims 1-3, 5-7 and 10-16 rejected under 35 USC 102(b) as being anticipated by Tennikova have been fully considered (Remarks, pg. 7, paragraphs 2 and 3) and are moot in view of withdrawn rejection necessitated by claim amendments. Applicant's arguments with respect to the

teachings of Tennikova as it pertains to the rejection made in this office action are addressed in section 14.

13. Applicant's arguments with respect to claim 1 rejected under 35 USC 102(b) as being anticipated by Hatch have been fully considered (Remarks, pg. 7, paragraphs 2 and 3) and are moot in view of withdrawn rejection necessitated by claim amendments. Applicant's arguments with respect to the teachings of Hatch as it pertains to the rejection made in this office action are addressed in section 14.

Claim Rejections - 35 USC § 103(a)

14. Applicant's arguments filed February 3, 2010 with respect to claims 1-4, 8 and 9 rejected under 35 USC 103(a) as being unpatentable over Tennikova in view of Urthaler or claims 1-16 over Hatch in view of Urthaler have been fully considered (Remarks, pg. 8, paragraph 3) and are moot in view of withdrawn rejection necessitated by claim amendments.

Applicant's arguments with respect to the teachings of Tennikova and Hatch as it pertains to the rejection made in this office action are addressed below.

Applicant argues that neither Tennikova nor Hatch teach or suggest monolith structure capable of adsorbing nucleic acids in the presence of potassium ions and is capable of releasing nucleic acids in an essentially salt free solution. Applicant further asserts that Tennikova's monolith structure uses an elution buffer containing salt in each example (see Figs. 5-10 for example). Likewise, Hatch teaches the use of gradient

elution utilizing salts such as triethylammonium acetate and tetrapropylammonium bromide (Remarks, pg. 7, paragraph 2). The Examiner acknowledges that neither Tennikova nor Hatch teach or suggest the functional limitation of the monolith structure. However, the arguments are based on the intended use of the monolith structure because as described above in section 9, neither the potassium ions nor the salt free solution are structural components of the claimed apparatus and therefore do not further define the apparatus (MPEP 2114). Even if the Applicant amends the claim requiring the potassium ions or the salt free solution as the structural components of the apparatus, as described above these structural components are taught by Sauer.

Furthermore, it is noted that in KSR, the Supreme Court particularly emphasized "the need for caution in granting a patent based on the combination of elements found in the prior art," (USPQ2d at 1395), and reaffirmed principles based on its precedent that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." In the instant case, nucleic acid adsorption to silica membrane in the presence of potassium ions and eluting the bound nucleic acid from the membrane with pure water (i.e., salt free solution) are familiar products for nucleic acid separation and purification which are very routinely practiced in the art, which are known to produce expected results. Therefore, the allegedly asserted structural components of potassium ions and salt free solution and the claimed apparatus are obvious over Tennikova, Hatch and Sauer.

Applicant further argues that none of the cited references teach or suggest selection of a specific macro-pore size according to the size of the nucleic acid molecule

to be purified. Applicant further asserts that Tennikova only provides for variation in the thickness of the monolith to adjust the separation of oligonucleotides of 8 to 14 bases. No teaching or suggestion is made by Tennikova of purifying nucleic acids of greater length, nor does Tennikova teach or suggest varying the size of the macropores to purify nucleic acids of various lengths (Remarks, pg. 7 paragraph 3). These arguments are not persuasive because claim 1 is rejected over combination of references. As described above in section 9, Examiner acknowledges that Tennikova does not teach variation of macropore size according to the size of the nucleic acids, which is taught by Hatch.

Applicant further argues that Hatch does not teach or suggest a variation in pore size according to the size of the nucleic acid to be purified. Hatch only provides for the separation of nucleic acids with one composition for nucleic acids of 17 base pairs to 3 kilo base pairs (Hatch, Column 8, lines 5-8 and 20-21; Remarks, pg. 7 paragraph 3).

The examiner acknowledges that though both Tennikova and Hatch use single monolithic column for the separation of nucleic acids, as described above in section 9, Hatch specifically teaches that the column designed for separation of DNA of about 300 bp requires an interstitial distance of 1 um, whereas for separation of 1,000 bp DNA require an interstitial distance of about 1 to 3 um (column 3, lines 38-54), suggesting a selecting the interstitial distance according to the size of the nucleic acids. Hatch also teaches selecting monolithic column having pores of about 1 um for separating DNA products of 2,072, 2,647, and 3,147 base pairs in length (column 8, lines 1-30). Hatch also teaches selecting C6 and C12 monolithic column for separating single and double

stranded nucleic acids (Figs. 1 to 3; Example 1 and 2). One having ordinary skill in the art would recognize that based on the combined teachings of requiring different pore size for separating different size nucleic acids and selecting the monolithic column with pore diameter of 1 um for separating different size of nucleic acids of Hatch encompasses monolithic structure corresponding to the size of the nucleic acids. Therefore Applicant's arguments regarding Hatch not teaching or suggesting a variation in pore size according to the size of the nucleic acid are not persuasive.

Furthermore, the claim as recited neither specifies the monolithic structure having specific pore diameter for specific size of the nucleic acid nor selecting a plurality of monolith structures for separating different sizes of nucleic acids. Claim as recited merely requires "an integrated monolith structure" for separating and purifying nucleic acids (Emphasis is underlined by the Examiner). Therefore monolith structure comprising macropores having a diameter of 5,000 nm to 100nm (i.e., macropore, micropore combination) of Hatch meets the structural limitation of the apparatus of claim 1. For these reasons, arguments that Hatch only provides one composition for nucleic acids of 17 base pairs to 3 kilo base pairs for the separation of nucleic acids are not persuasive because they are not commensurate with the scope of the claim.

Conclusion

15. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NARAYAN BHAT whose telephone number is (571)272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Narayan K. Bhat

Examiner, Art Unit 1634

/Steven C Pohnert/

Primary Examiner, Art Unit 1634